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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,432	04/06/2001	Alexandre M. Izmailov	VGEN.P-066	6093

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,432

Applicant(s)

IZMAILOV ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 26, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed November 12, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The addition of new claims 10-20 and the withdrawal of claim 9 have been acknowledged.
3. The new title and abstract, filed July 26, 2004, have been accepted.
4. Claims 1-8 and 10-21 are examined on the merits.
5. NON-FINAL OFFICE ACTION.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1-8 and 10-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Specific to claim 1, step (a), the limitation of "set of three or more alignment points", and step (c) recites the aligning step which causes claim 1 to be vague and indefinite. Claim 1 is not clear as to whether step (c) is a realigning of the already aligned points selected in step (a). Alternately, are the points directed to trace data to be aligned by step (c) for the first

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time? The same issue is present in claims 5 and 10. Claims 2-4, 6-8, and 11-21 are rejected for being dependent from claim 1, 5, or 10.

9. Specific to claim 1, lines 9-10, the phrase “the alignment point” lacks clear antecedent basis because all previous citations are directed to plural points. The claim is unclear as to whether a reference position number is assigned for each of the plurality of alignment points. Or is there some specific alignment point meant by said phrase but is not clearly set forth in the claim? The same issue is present in claims 5 and 10. Claims 2-4, 6-8, and 11-21 are rejected for being dependent from claim 1, 5, or 10.

10. Specific to claim 4, the phrase “nucleotide base type” in line 2 causes said claim to be vague and indefinite because it is unclear whether the limitation of “nucleotide base type” is directed to natural or synthetic nucleotide base type. Further, the limitation of “nucleotide base type” is not clear because said limitation could reasonably be construed as being directed to the RNA or DNA nucleotide base type. The same issue is present in claims 8, 13, and 17. Clarification of the metes and bounds is required.

11. Specific to claim 18, lines 1-2 recite the determining of a singular “spacing interval”, however, line 3 recites “said intervals” which causes the antecedent basis for the limitation to be unclear. The same issue is present in claims 19-21. Clarification of the metes and bounds is required.

CLAIM REJECTIONS - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Allex et al. (1997).

RESPONSE TO ARGUMENTS

14. Applicant's arguments directed to the 35 U.S.C. §103 rejection have been found to be unpersuasive. Therefore, said rejection has been withdrawn.

15. Allex et al. discloses a method for increasing consensus accuracy in DNA fragment assemblies by directly incorporating aligned ABI trace information into consensus calculations via previously described representation, Trace-Data Classifications (Allex et al. 1996) (page 1, column 1, Abstract etc., and Introduction §).

16. The inclusion of Allex et al. (1996) is not being used as prior art but only to expand on the cited description of Trace-Data Classifications.

17. Allex et al. (1996) discloses there are four sets of data for a fragment of DNA, one for each of the four fluorescent dye. Each set of base trace-data is composed of about ten to 15 data points representing the intensities (peaks) of the fluorescent dyes (page 5, column 2, Trace-Data Representation, to page 6, column 2). The data is derived from a highly conserved E. coli genome (target) (page 10, columns 1-2, Data Sets §), as in instant claims 1, 5, and 10, step (a).

18. Allex et al. (1996) discloses trace data associated with a single base may contain a peak, or a valley, or both a peak and a valley. The base is called at a particular point in the trace data – we assign scores for both the peak and the valley that are the closest to this location. These class scores are weighted by proximity to the base-call location. Peaks or valleys that

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are closer to where the base is called have a relatively higher score than those that are further away. Sometimes we may need to make comparisons among the four sets of trace data associated with a single base call (same type). For this situation, the classification scores are adjusted to reflect the relative difference in intensities (heights) of the peaks or valleys; higher peaks score higher than lower peaks, and lower valleys score higher than higher valleys (page 5, column 2, Trace-Data Representation §, to page 7, line 13), as in instant claims 1, 5, and 10, step (b).

19. Alex et al. discloses the alignment of E. coli trace data from Alex et al. (1996) (page 4, column 1, Algorithmic Details, to page 6, Method §), as in instant claims 1, 5, and 10, step (c).

20. Alex et al. discloses evidence of traces (Figure 4) comprising ACGT which represents a “heterogeneous multiplets” as defined by the specification on page 7. The citation above anticipates the instant claims 2, 3, 6, 7, 11, and 12.

21. There are four sets of data for a fragment of DNA, one for each of the four fluorescent dye. Each set of base trace-data is composed of about ten to 15 data points representing the intensities (peaks) of the fluorescent dyes (page 5, column 2, Trace-Data Representation, to page 6, column 2), as in instant claims 4, 8, and 13.

CONCLUSION

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO’s official fax number is (571) 273-8300.

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23. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

24. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly
1/31/05

 1/31/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER